K111578
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510(k) Summary

SEP 2 3 2011

Submitted by:	Coreleader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Sintai 5th Rd., Sijhih District, New Taipei city, Taiwan(R.O.C), 22102 Phone: +886-2-26968880 FAX: +886-2-26968882
Contact Person:	Teeming Tsao
Date Prepared:	May 25, 2011
Proprietary Name:	Coreleader Colla-Algi Fiber
Common Name:	Topical Wound dressing
Classification:	Unclassified
Classification Name:	Dressing, Wound
Predicate Device:	Coreleader Colla-Algi Fiber Dressing is substantially equivalent to: FIBRACOL COLLAGEN-ALGINATE DRESSING (K925548). Manufactured by JOHNSON & JOHNSON MEDICAL, INC. FIBRCOL PLUS COLLAGEN WOUND DRESSING WITH ALGINATE (K982597). Manufactured by JOHNSON & JOHNSON MEDICAL, INC. KALTOSTAT FORTEX WOUND DRESSING (K921009). Manufactured by CALGON VESTAL DIV. KALTOSTAT WOUND DRESSING (K910059). Manufactured by CALGON VESTAL DIV.
Device Description:	Coreleader Colla-Alig Fiber Dressing with Alginate is wound care dressing with 10% collagen composition. Colla-Alig Fiber Wound Dressing with Alginate combines with exudate to maintain a moist wound environment.

The moist environment provided by the Colla-algi fibers may provide an environment favorable to the wound healing process. It is non-adherent, removes easily and leaves wound free of fiber. It maintains initial integrity when wet. Soft, conformable sheet can be cut to fit any size wound.

Biocompatibility studies have demonstrated the Coreleader Colla-Algi Fiber Dressing to be non-irritating, non-sensitizing, and non-cytotoxic.

Coreleader Colla-Algi Fiber Dressing is a sterile topical wound dressing, packed in a pouch and a foil bag, and sterilized by gamma-ray radiation to a 10^{-6} SAL.

Intended Use:

Coreleader Colla-Algi Fiber Dressing is indicated for management of exuding wounds including Full-thickness and partial-thickness wounds, Pressure ulcers, Venous ulcers, Ulcers caused by mixed vascular etiologies, Diabetic ulcers, Second-degree burns, Donor sites and other bleeding surface wounds, Abrasions and Traumatic wounds healing by secondary intention, Dehisced surgical incisions.

Technological Characteristics:

Coreleader Colla-Algi Fiber Dressing with Alginate is an advanced wound care device composed of collagen and calcium alginate fibers. Its unique combination of natural biopolymers created by Wet-Spinning process combines the structure support of collagen and gel forming properties of alginates into a sterile, soft, absorbent, conformable topical wound dressing. The dressing is manufactured from bovine collage and medical grade alginate.

The source of bovine collagen is from bovine hide splits from Australia. The hides are from healthy cattle slaughtered under process further in a controlled clean room in order to avoid the possibility of bovine spongiform encephalopathy (BSE) contamination. The collagen is linked with the calcium alginate using a Wet-Spinning process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Coreleader Biotech Co., Ltd.
% Mr. Ian Li
19F, No. 100, Sec. 1, Sintai 5th Rd
Sijhih Dist., New Taipei City
Taiwan (R.O.C) 22102

SEP 23 2011

Re: K111578
Trade/Device Name: Coreleader Colla-Algi Fiber
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 16, 2011
Received: August 26, 2011

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin E. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111578

Device Name: Coreleader Colla-Algi Fiber

Indications For Use:

Coreleader Colla-Algi Fiber Dressing is indicated for management of exuding wounds including:

- Full-thickness and partial-thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second-degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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